Docket No. 22956-214
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:	
Shelby L. Cook et al.	Confirmation No. 9377
Application No. 10/615,625	Art Unit: 3731
Filed: June 27, 2003	Examiner: Tuan Van Nguyen
For: BIOABSORBABLE SUTURE ANCHOR SYSTEM FOR USE IN SMALL JOINTS	

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Dated: February 26, 2010 Signature: _____
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APPEAL BRIEF PURSUANT TO 37 C.F.R. § 41.37

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I. REAL PARTY IN INTEREST

The real party in interest is Ethicon, Inc. of Somerville, New Jersey, which derives its rights in this application by virtue of an assignment of the application by the inventors to Ethicon, Inc. as recorded at Reel 014720, Frame 0075.

II. RELATED APPEALS AND INTERFERENCES

None.

III. STATUS OF CLAIMS

Claims 1-5 and 8-19 are currently pending and stand rejected in the present application. Claims 6, 7, and 20-25 were previously canceled. Accordingly, claims 1-5 and 8-19 are subject to this appeal.

IV. STATUS OF AMENDMENTS

No amendments were made subsequent to the final Office Action mailed on January 4, 2010.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention provides suture anchors for anchoring tissue to a bone that are configured to toggle and anchor inside a bone cavity based on tension being applied to a suture located in a suture channel of the anchors. The suture channel is formed so that it is oriented substantially transverse at right angles to a longitudinal axis of symmetry of an elongate body of the anchor, and further, so that it is laterally offset with respect to the longitudinal axis in a direction opposite to a direction of a flared portion formed on a second, trailing end of the suture anchor. The anchor can also be included as a component of a system for anchoring tissue to a bone that further includes a length of suture thread and a suture anchor insertion tool, and additionally, the anchor can be used in a method of attaching tissue to a bone in a patient's body.

A. Independent Claim 1 Recites a Suture Anchor for Anchoring Tissue to a Bone

Independent claim 1 recites a suture anchor for anchoring tissue to a bone. By way of non-limiting examples, FIGS. 1, 2A, and 2B, which are reproduced below, illustrate one embodiment of such a suture anchor and FIGS. 3, 4A, and 4B illustrate a second embodiment of such a suture anchor. The suture anchors 10, 110 each include an elongate body 12, 112 defined by a longitudinal axis of symmetry L, a first, leading end 14, 114, and a second, trailing end 16, 116, a flared portion 24, 124 formed on the second end 16, 116, and a suture channel 32, 132 formed in the elongate body 12, 112 for passage of a suture strand therethrough. Page 5, lines 2-9 and 26-27 and page 6, lines 13-15 of the Application as filed ("the Application"). The elongate body 12, 112 includes two opposed surfaces 20, 120 between the first end 14, 114 and the second end 16, 116 and a plurality of sidewalls 22, 122 extending between the two opposed surfaces 20, 120. *Id.* at page 5, lines 6-8 and page 6, lines 13-15. The flared portion 24, 124 extends from one of the sidewalls 22, 122 and is adapted to engage and anchor into bone tissue. *Id.* at page 5, lines 8-14 and page 6, lines 13-15. The suture channel 32, 132 extends between the two opposed surfaces 20, 120, is substantially transverse at right angles to the longitudinal axis of symmetry L of the body 12, 112, and has a centerline that is laterally offset with respect to the longitudinal axis of symmetry L of the body 12, 112 in a direction opposite to the direction of the flared portion 24, 124. *Id.* at page 5, line 27 to page 6, line 15. Each of the suture anchors 10, 110 as recited is configured to toggle and anchor inside a bone cavity based on tension being applied to a suture in the suture channel 32, 132. *Id.* at page 6, lines 9-15.

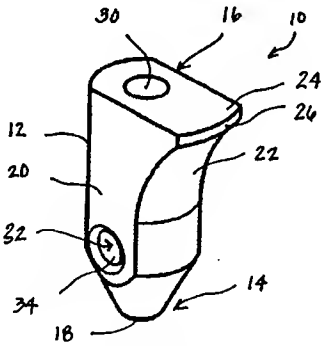


FIG. 1

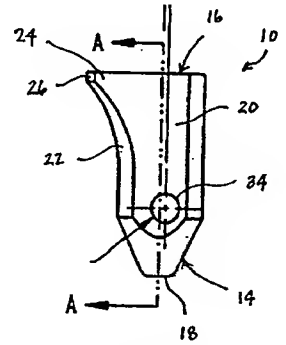
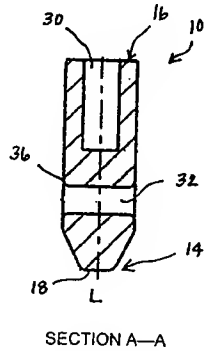


FIG. 2A



SECTION A—A
FIG. 2B

B. Independent Claim 15 Recites a System for Anchoring Tissue to a Bone

Independent claim 15 recites a system for anchoring tissue to a bone. By way of a non-limiting example, FIGS. 5A-5C, which are reproduced below with typed reference numbers, illustrate one embodiment of a system 200 that includes a bioabsorbable suture anchor 10, a length of suture thread 206 attached to the suture anchor 10, and a suture anchor insertion tool 210. *Id.* at page 10, line 4 to page 11, line 13. The suture anchor 10 includes all of the features discussed above with respect to claim 1 and further includes a bore 30 extending into the elongate body 12 from the second, trailing end 16. *Id.* at page 10, lines 4-6 and page 5, lines 21-22. The suture anchor insertion tool includes an elongate member 212 with a proximal, handle end (not shown) and a distal attachment end 214. *Id.* at page 10, lines 19-22.

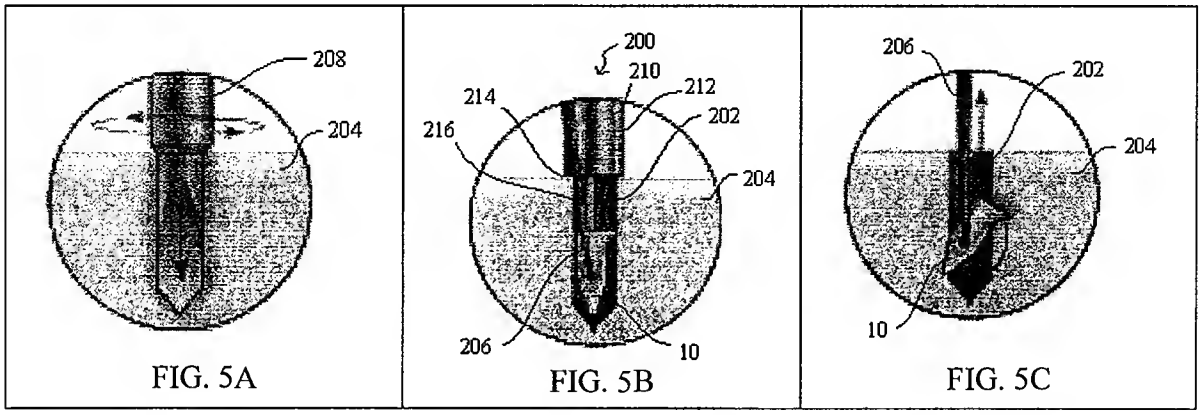


FIG. 5A FIG. 5B FIG. 5C

C. Independent Claim 19 Recites a Method of Attaching Tissue to a Bone

Independent claim 19 recites a method of attaching tissue to a bone in a patient's body. By way of a non-limiting example, FIGS. 6A-6C, which are reproduced below with typed reference numbers, illustrate one embodiment of a method that includes providing a system 200 for anchoring tissue to bone that includes a bioabsorbable suture anchor 10 and a length of suture thread 206 attached to the suture anchor 10, forming a bone cavity 202 in the bone where the tissue is to be anchored, securing the suture strand 206 of the system 200 to a portion of tissue to be attached to the bone, inserting the suture anchor 10 at least partially within the bone cavity 202, and toggling the suture anchor 10 by pulling on the attached suture strand 206 such that a

flared portion 24 of the anchor 10 penetrates into an inner surface of the bone cavity 202. *Id.* at page 11, lines 2-13 and 19-27. The suture anchor 10 of the system 200 includes all of the features discussed above with respect to claim 1. *Id.* at page 10, lines 4-6.

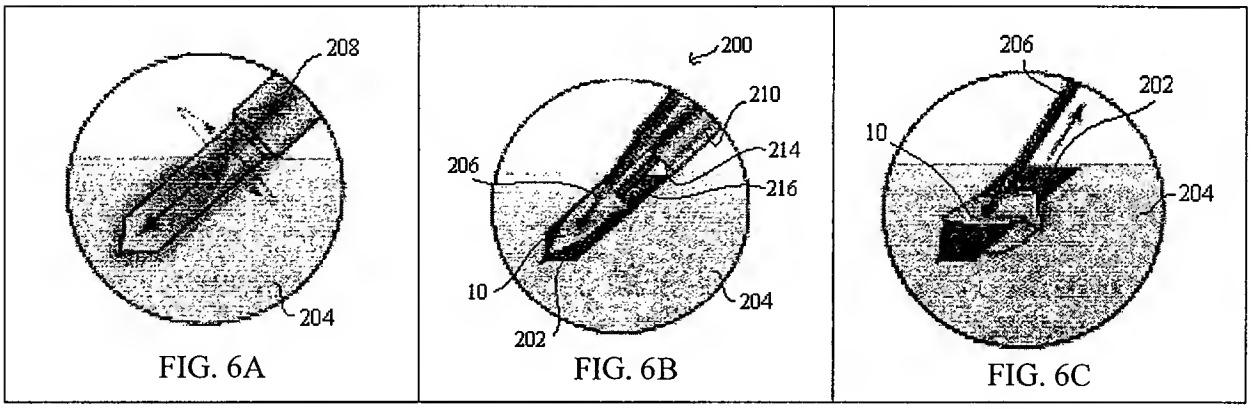


FIG. 6A FIG. 6B FIG. 6C

D. Dependent Claims 2, 3, 17, and 18 Recite Particular Dimensions of the Suture Anchor

Claim 2 recites a suture anchor 10, 110 in which a length of the elongate body 12, 112 is in the range of about 2 to about 6 mm. *Id.* at page 7, lines 5-6. Similarly, claim 17 recites a system 200 in which a length of the elongate body 12 of the suture anchor 10 is in the range of about 2 to about 6 mm. *Id.*

Claim 3 recites a suture anchor 10, 110 in which a width of the second trailing end 16, 116 is about 1 mm to about 3 mm at its widest portion. *Id.* at lines 6-7. Similarly, claim 18 recites a system 200 in which a width of the second trailing end 16 of the suture anchor 10 is about 1 mm to about 3 mm at its widest portion. *Id.*

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

There are two grounds of rejection to be reviewed on appeal.

A. Rejections Under 35 U.S.C. § 103(a) of Claims 1-5 and 8-19

The Examiner has rejected claims 1-5 and 8-19 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,270,518 to Pedlick et al. in view of U.S. Patent No. 5,626,612 to Bartlett.

B. Rejections Under 35 U.S.C. § 103(a) of Claims 2, 3, 14, 17, and 18

The Examiner has rejected claims 2, 3, 14, 17, and 18 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 7,320,701 to Haut et al.

VII. ARGUMENT

Applicants traverse each of the bases for rejecting the claims.

A. To Rebut Obviousness Rejections, It Is Important to Understand the Context in which the Invention Was Made

To fully understand the claimed invention, it is first necessary to appreciate the state-of-the-art at the time of Applicants' invention, which represents the background against which the claimed invention was developed.

1. The Problem Addressed by the Invention Is the Creation of a Toggling Suture Anchor for Use in Small Bones

A number of devices and methods have been developed to attach soft tissue to bone. These include screws, staples, cement, suture anchors, and sutures alone. Some of the more successful methods involve use of a suture anchor to attach a suture to the bone, and tying the suture in a manner that holds the tissue in close proximity to the bone. Page 1, lines 22-25 of the Application.

While suture anchors for reattaching soft tissue to bone are known in the art, they are typically sized and dimensioned for use in large bone joints such as the patient's shoulder or knee. Where the need arises to reattach tissue to a relatively small bone in the patient's body, such as in the hand or the skull, the anchors currently available would be too large for the insertion depth desired. *Id.* at page 2, lines 10-14.

Suture anchors that were used in small spaces prior to the invention primarily relied upon screws, threads, and barbs to attach tissue to bone. While some forms of toggling suture anchors were known for use in large bones prior to the invention, Applicants were not aware of any

suture anchors that were capable of toggling in such small spaces as the recited suture anchors can at the time of the invention. This was because the structures in which the suture anchors were used were too small to handle the types of toggling suture anchors that were known. Prior to the present invention, it was not known how to design a suture anchor that was small enough to work in those structures and also toggle. As a result, those of ordinary skill in the art instead developed non-toggling anchors for use with such small bones, such as anchors with threads and screws. Paragraph 7, pages 3-4 of the Declaration of Jose E. Lizardi Pursuant to Rule 132 filed on January 22, 2008 ("the Lizardi Declaration"), which is attached hereto as Exhibit A; *see also* references cited in paragraph 7 on pages 3-4 of the Lizardi Declaration.

Accordingly, at the time of the invention, there was a need for a suture anchor that was suitably dimensioned and configured for reattaching soft tissue to bone in small joints of a patient such as in a hand or skull that was capable of toggling. *Id.* and page 2, lines 14-16 of the Application.

2. The Invention Solves the Problem Both by Creating a Suture Anchor Capable of Toggling that Is Smaller than Those on the Market and by Configuring the Suture Channel as Claimed

The present invention solves the problem of creating a suture anchor that is capable of toggling for reattaching soft tissue to bone in small joints by engineering a suture anchor that is both smaller than anchors on the market and which includes a suture channel that is oriented to be transverse to and longitudinally offset with respect to a longitudinal axis of the body of the anchor. The claimed suture anchors, systems for anchoring tissue to a bone, and methods of attaching tissue to a bone are thus useful in a variety of different procedures, including in the repair or reconstruction of collateral ligaments, flexor and extensor tendon at the proximal interphalangeal (PIP), distal interphalangeal (DIP), and metacarpal interphalangeal (MIP) joints of all digits in a patient's hand, and for attaching soft tissue to the parietal, temporal ridge, frontal, mandible, maxilla, zygoma, and periorbital bones of the skull. The anchors, systems, and methods are particularly useful in these types of procedures because of their small size and their geometry. Paragraph 6, pages 2-3 of the Lizardi Declaration.

More particularly, the anchor comprises an elongate body defined by a longitudinal axis, a first, leading end, and a second, trailing end. The elongate body also has two opposed surfaces extending between the first and second ends, and a plurality of sidewalls extending between the two opposed surfaces. The first, leading end can be tapered and extend into a blunt tip having a continuous surface, which the second, trailing end can be wider than the first end such that one of the sidewalls is flared. The suture anchor also includes a suture channel that extends between the two opposed surfaces. The suture channel is formed in the elongate body to allow the passage of a suture strand therethrough, and it is preferably oriented to be ***transverse to the longitudinal axis of the anchor***. The suture channel is flanked, or bordered, on each side by an opening that is located on an opposed surface. The center of each of the openings is ***laterally offset with respect to the longitudinal axis of the elongate body***, and in particular, the openings are laterally offset ***on the opposite side of the longitudinal axis when compared to the flared portion of the second, trailing end***. The offset channel enables a surgeon to toggle the suture anchor ***by pulling on an attached suture strand*** while the anchor is inside a bone cavity so that the flared portion toggles into the bone. *Id.* and page 2, line 19 to page 3, line 13 of the Application; *emphasis added.*

Accordingly, the present invention is directed to a toggling suture anchor that can be used to attach tissue to small bones and joints, as well as systems and methods related to the same, because the anchor is smaller than toggling suture anchors used prior to the invention and the suture channel of the anchor is configured in such a manner that toggling can occur in small bones and joints. *Id.*

B. Claims 1, 15, and 19, as well as the Claims that Depend Therefrom, Are Not Obvious Over Pedlick in View of Bartlett

The configuration of the claimed suture anchor, which is independently claimed (claim 1), is a portion of an independently claimed system (claim 15), and is included in a system that is provided as part of a method of attaching tissue to a bone in a patient's body (claim 19), is critical to the success of the claimed invention. The configuration of the claimed suture anchor includes a particular design and location of a suture channel of the claimed suture anchor. In particular, by forming a suture channel in an elongate body of a suture anchor that is oriented

substantially transverse at right angles to a longitudinal axis of symmetry of the body and which has a centerline that is laterally offset with respect to the longitudinal axis of symmetry of the body in a direction opposite to the direction of a flared portion of the anchor, the anchor is capable of toggling inside a bone cavity based on tension being applied to a suture in the suture channel.

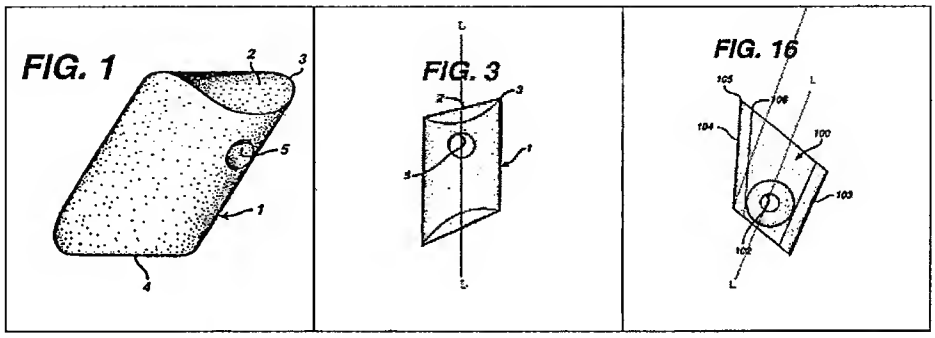
1. The Scope and Content of the Prior Art

To fully understand the obviousness rejection, it is first necessary to understand the scope and content of the cited prior art.

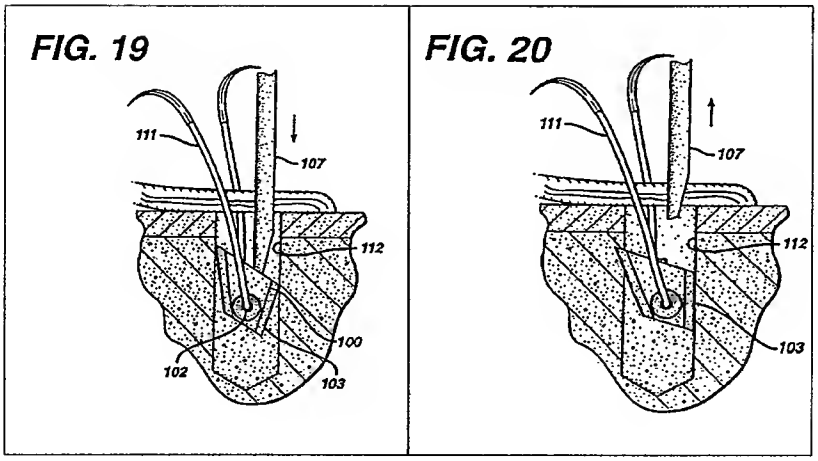
a. Pedlick Teaches a Wedge Shaped Suture Anchor in which the Suture Channel Is Aligned with the Longitudinal Axis of Symmetry of the Suture Anchor Body

U.S. Patent No. 6,270,518 to Pedlick et al. ("Pedlick") discloses a wedge shaped suture anchor for anchoring suture material to bone. Col. 1, lines 1-2 and 9-11. As shown in FIG. 1, which is reproduced below, one embodiment of a suture anchor 1 includes a first abutment end 2 and a second abutment end 3. Col. 8, lines 50-54. The suture anchor has a substantially cylindrical cross-section and the cylindrical longitudinal surface forms with the abutment end 2 a corner 4. *Id.* at lines 54-57. A suture opening 5 is defined by the body of the suture anchor 1. *Id.* at lines 60-62. In an alternative embodiment, shown in FIG. 3 and reproduced below with a longitudinal axis of symmetry of the body L added, the first abutment end 2 and second abutment end 3 are slightly tapered to a point or edge. *Id.* at lines 62-64. The suture opening 5 is formed transverse to the longitudinal direction of the suture anchor 1, and as shown below, is aligned with a longitudinal axis of symmetry of the body L. *Id.* at lines 65-67. In yet another embodiment, shown in FIG. 16 and reproduced below with both a longitudinal axis of symmetry of the body L and a line that defines the elongate body from the flared portion so that the axis of symmetry for the body can be determined added, a suture anchor 100 has a body formed in a substantially truncated wedge shape. Col. 9, lines 63-65. The body defines a suture opening 102 and includes an abutment wall 103 and a plow wall 104 that forms an edge 105 at its intersection with top 106 of the anchor 100. Col. 9, line 65 to col. 10, line 12. As shown below, the suture

opening 102 is aligned with a longitudinal axis of symmetry of the body L. The axis of symmetry of the body L is drawn to define symmetry of the body, excluding the edge 105 in light of the longitudinal axis of symmetry of the elongate body of the claimed invention, which is determined without consideration of the flared portion. Further, a length of the top 106 is about 4.6 millimeters, the abutment wall 103 has a length of about 3.2 millimeters, and the plow wall 104 has a length of about 3.6 millimeters. Col. 11, lines 59-62.



Pedlick also discloses a method of implanting a wedge shaped suture anchor for anchoring suture material to bone. Col. 1, lines 1-2 and 9-11. As shown in FIG. 19, which is reproduced below, the suture anchor 100 has a shaft 107 attached thereto and is inserted into a bore hole after threading a suture 111 through the suture opening 102. Col. 11, lines 40-44. After the suture anchor 100 is positioned at a desired location in the hole and an applier is inserted, the shaft 107 is drawn upward, as shown in FIG. 20, which is reproduced below, forcing the edge 105 (not labeled) to dig into the softer cancellous layer of the bone. *Id.* at lines 44-50. The resulting rotation of the body of the suture anchor, in combination with the withdrawal tension, breaks a frangible portion to allow the shaft 107 to separate from the anchor 100, thereby permitting removal of the shaft 107. *Id.* at lines 50-54.



b. Bartlett Teaches an Apparatus for Anchoring Sutures in which a Location of the Suture Channel Is Configured to Have the Smallest Effect on the Strength of the Suture Anchor

U.S. Patent No. 5,626,612 to Bartlett ('Bartlett") discloses an apparatus for anchoring sutures to a live human bone. Col. 1, lines 10-11. As shown in FIG. 7, which is reproduced below, in one embodiment a suture anchor 722 has an elongate shape of a two cone combination in which a "central axis" is formed between the apex of the cone and the center of the fixed curve that forms the directrix of the cone. Col. 4, lines 49-62. The anchor 722 includes a first conical surface 740, a central axis 25, an anchor bore 34 across the conical surface, and a base that includes a second conical surface 742 inverted with respect to the first conical surface. Col. 7, lines 60-67. The anchor bore 34 is for positioning an insertion tool therein to insert the suture anchor into the patient bone hole. Col. 6, lines 54-56. The suture may be threaded through the anchor bore 34 alongside the insertion tool. Col. 7, lines 4-6. Alternatively, a separate suture accessory bore 36 may be formed substantially perpendicular to the anchor bore 34 for separately accommodating the suture. *Id.* at lines 7-10. The accessory bore 36 minimizes contact between the suture and the insertion tool during the insertion process. Col. 8, lines 44-50. As detailed by Bartlett:

> The location of accessory bore 36 is ***selected to have the smallest effect on the strength of the suture anchor*** because of the deficit of suture anchor material. One of ordinary skill in the art can determine, by routine experimentation and

> an analysis of the geometry of the suture anchor, the optimum point at which accessory bore 36 can be placed ***without detrimentally effecting the strength of the suture anchor.***

Id. at lines 53-60; *emphasis added.* A length of the suture anchor is approximately 1.156 cm, and a diameter is preferably approximately 0.297 cm. Col. 5, lines 31-36.

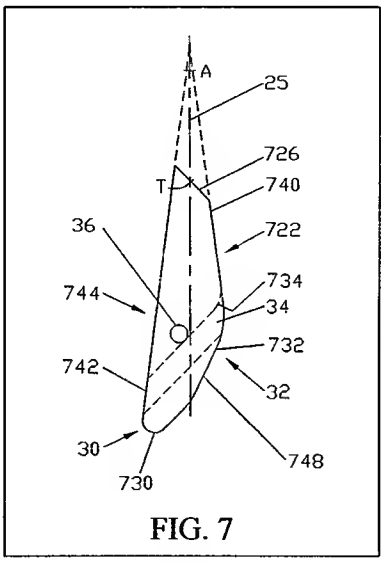


FIG. 7

Bartlett also discloses a method for anchoring sutures to a live human bone. Col. 1, lines 10-11. A suture anchor 20 (although the specification discusses the method with respect to anchor 20, col. 10, lines 46-49 indicates that anchor 722 can be used in the method) is mounted on an insertion end 44 of an insertion tool 40 by securely positioning the insertion end 44 within the anchor bore 34. Col. 10, lines 60-67. The anchor 20 is inserted into a patient bone hole 70, and once the conical surface extending between a leading edge 30 and an apex 24 encounters the patient bone hole 70, the suture anchor 20 begins to rotate or reorient in order to fit into the patient bone hole 70. Col. 11, lines 10-20. A main body 42 of the insertion tool 40 is maintained parallel to the patient bone hole 70, and thus, when the suture anchor 20 reorients, the insertion end 44 bends. *Id.* at lines 20-23. As the suture anchor 20 continues to be inserted into the bone hole 70, eventually a trailing edge 32 of the anchor 20 bypasses a cortical bone tissue 74 and begins traveling through cancellous bone tissue 76 surrounding the bone hole 70, thereby allowing the insertion end 44 of the insertion tool 40 to begin resuming its initially straight configuration and deploying the suture anchor. *Id.* at lines 24-33. Once the apex 24 clears the

cortical bone tissue 74, the entire suture anchor is in cancellous bone tissue 76 and the insertion end 44 returns to its original configuration. *Id.* at lines 34-37. The suture anchor 20 can then be secured in its final position and then the insertion tool 40 can be disengaged from the suture anchor and removed. *Id.* at lines 37-42.

c. The Examiner Argues that Bartlett Remedies the Deficiencies of Pedlick by Disclosing a Suture Channel that is Laterally Offset from the Longitudinal Axis of the Anchor

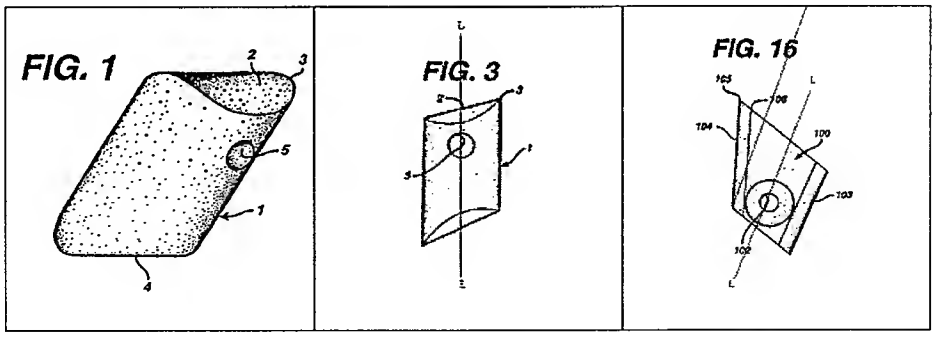
The Examiner argues that Pedlick discloses the invention substantially as claimed except for a suture channel that is laterally offset from the longitudinal axis of the anchor in a direction opposite the direction of the flared portion. Paragraph 12, page 5, lines 14-16 of the Office Action dated January 4, 2010 ("the Office Action"). The Examiner relies on Bartlett to overcome the deficiencies of Pedlick. *Id.* at lines 16-21. In making the rejection, the Examiner argues that Pedlick does disclose a suture opening or channel 5, as shown in FIG. 1, that is offset from the center of the anchor for the purpose of toggling the anchor and that Bartlett discloses a suture anchor that includes a suture channel 36 that is laterally offset from the longitudinal axis of the anchor. *Id.* Stating that it would have been obvious to substitute one known element for another, the Examiner argues that it would have been obvious to substitute the hole of the Pedlick device with the hole disclosed by Bartlett such that the hole is offset from the center of the anchor ***for the purpose of toggling the anchor and preventing a detrimental effect on the strength of the suture anchor***. *Id.* at page 6, lines 1-7; *emphasis added.* Further, the Examiner also states that Applicants have failed to disclose that the recited suture channel provides an advantage or solves a stated problem. *Id.* at paragraph 13, page 6, lines 8-14.

2. *Pedlick in View of Bartlett Fails to Render Obvious Independent Claims 1, 15, and 19*

Independent claims 1, 15, and 19, as well as claims 2-5, 8-14, and 16-18 which depend therefrom, are patentable over Pedlick in view of Bartlett at least because the Examiner's proposed combination does not teach or even suggest the claimed invention, there is no rational reason to make the Examiner's proposed combination, and in light of secondary considerations it cannot be said that the claimed invention was obvious at the time of the invention.

a. Pedlick in View of Bartlett Fails to Teach or Even Suggest a Suture Channel Having a Centerline that Is Laterally Offset with Respect to the Longitudinal Axis of Symmetry of the Body in a Direction Opposite to the Direction of the Flared Portion

The suture anchor of claim 1, of the system for anchoring tissue to a bone of claim 15, and of the method of attaching tissue to a bone in a patient's body of claim 19, each recites a suture channel having a centerline that is laterally offset with respect to the longitudinal axis of symmetry of the body in a direction opposite to the direction of the flared portion. The Examiner agrees that Pedlick fails to teach or even suggest a suture anchor having a suture channel as recited in each of claims 1, 15, and 19. Paragraph 12, page 5, lines 14-16 of the Office Action. To the extent that Pedlick does teach that the suture opening or channel 5 is offset from the center, such as the Examiner proposes by relying on FIG. 1, which is reproduced below, it is not ***laterally*** offset as clearly illustrated in the reproductions of FIG. 3 (which is a front view of the suture anchor of FIG. 1) and FIG. 16, which are also reproduced below. A longitudinal axis of the body of the suture anchor L directly intersects the centerline of the suture opening or channel 5, contrary to the recited suture channel.



Assuming for the sake of argument that there is motivation to combine the teachings of Bartlett to substitute the suture opening 5 of Pedlick for the suture channel 36 of Bartlett, such a combination still does not teach or even suggest the claimed invention. Not only does the recited suture channel need to be laterally offset with respect to the longitudinal axis of symmetry of the body, it has to be located ***in a direction opposite to the direction of the flared portion***. The anchor of Bartlett fails to teach or even suggest a flared portion as recited in claims 1, 15, and 19. The only portions of Bartlett that could conceivably be considered a flared portion are its leading

edge 730 and its trailing edge 732, but there are not two opposed surfaces therebetween and a plurality of sidewalls extending between the two opposed surfaces as required by the claims. Without a teaching of a flared portion as recited in claims 1, 15, and 19, Bartlett cannot teach or even suggest a suture channel that is laterally offset with respect to the longitudinal axis of symmetry of the body ***in a direction opposite to the direction of the flared portion***.

To the extent that Bartlett does teach where to place the channel, it suggests that the channel be placed so as to "have the smallest effect on the strength of the suture anchor." In Applicants' claimed anchor, this would presumably be toward (rather than away from as claimed) the flared portion as there is more mass of material there. Thus, to the extent that Bartlett can be said to teach anything about the location of the suture channel in a flared anchor, it teaches the ***opposite*** of what is claimed.

Accordingly, at least because the proposed combination does not lead to the recited configuration of a suture anchor having a suture channel having a centerline that is ***laterally offset*** with respect to the longitudinal axis of symmetry of the body ***in a direction opposite to the direction of the flared portion***, the Examiner's proposed combination does not render independent claims 1, 15, and 19 obvious.

b. Pedlick in View of Bartlett Fails to Teach or Even Suggest a Suture Anchor Configured to Toggle and Anchor Inside a Bone Cavity Based on Tension Being Applied to a Suture in the Suture Channel

The suture anchor of claim 1, of the system for anchoring tissue to a bone of claim 15, and of the method of attaching tissue to a bone in a patient's body of claim 19, each recites that the suture anchor is configured to toggle and anchor inside a bone cavity ***based on tension being applied to a suture in the suture channel***. In the most recent Office Action the Examiner fails to argue that either Pedlick or Bartlett discloses a suture anchor that is configured to toggle and anchor inside a bone cavity ***by the suture***. The Examiner only argues that the suture channel of Pedlick is offset from the center of the anchor for the purpose of toggling the anchor. Paragraph 12, page 5, lines 16-18. In a previous Office Action dated April 23, 2008, however, the Examiner argued that Pedlick discloses a suture anchor that is configured to toggle and anchor

inside a bone cavity by the suture. Paragraph 13, page 4, lines 23-24. The teachings of Pedlick disclose nothing of this nature, which is likely why the Examiner no longer asserts that Pedlick discloses a suture anchor that is configured to toggle and anchor inside a bone cavity ***by the suture***.

Pedlick teaches a wedge-shaped suture anchor that is adapted to receive an installation tool for insertion into a bone hole. In use, the user applies a downward pressure to the installation tool to position the anchor within the bone hole. Once positioned, the user ***releases*** this downward pressure in preparation for withdrawing the device, causing the shaft of the tool to straighten. This straightening force causes one of the edges of the anchor to press into the wall of the bone cavity. ***As a result***, the anchor pivots or rotates within the bone hole such that the anchor securely engages the wall of the one hole. Col. 11, lines 40-54; *emphasis added.* This method is further described in detail at col. 19, lines 33-41:

> Next, the user withdraws installation tool 400 from bore hole 600. As downward pressure on installation tool 400 is released (to be replaced by opposite upward pressure during tool withdrawal), the flexed shaft tip 404 tries to straighten itself, causing the suture anchors sharp, well-defined biting edge 322 to press into wall 602, and causing the suture anchor to pivot slightly in the bore hole so that the suture anchor's cam surface 326 securely engages wall 606 of the bore hole. As the user retracts installation tool 400 from bore hole 600, rearward movement of installation tool 400 causes progressively more distal portions of the suture anchor's cam surface 326 to come into engagement with wall 606 of the bore hole.

See also, col. 9, lines 17-38 (for the embodiment illustrated in FIGS. 9 and 10), col. 9, lines 39-62 (for the embodiment illustrated in FIGS. 11 and 12), col. 11, lines 40-56 (for the embodiment illustrated in FIGS. 19-25), and col. 12, lines 61-65 (for the embodiment illustrated in FIG. 26). ***In every one of the many embodiments in Pedlick, it is the installation tool that rotates the anchor.***

The Examiner does maintain that Pedlick discloses a suture opening or channel that is offset from the center of the anchor "for the purpose of toggling the anchor." Paragraph 12, page 5, lines 16-18 of the Office Action. The Pedlick anchor's offset, however, is never laterally offset as recited. To the extent that Pedlick teaches that the suture channel 5 can be longitudinally offset from the center, it teaches that this configuration creates an imbalance in the rotation of the device on implantation that makes it easier for the ***inserter tool*** to impart rotation to the anchor. Col. 8, line 67 to Col. 9, line 38. Thus, rather than teaching a configuration for toggling based on tension from a suture in the channel, Pedlick teaches a configuration that promotes toggling by the inserter tool. Pedlick teaches neither Applicants' structure nor Applicants' function.

Bartlett fails to remedy the deficiencies of Pedlick because it too relies on an insertion tool to toggle and anchor the suture anchor inside a bone cavity. In use, the user mounts the insertion end of the insertion tool into the anchor bore of the anchor and inserts the combination into a patient bone hole. As the anchor progresses in the bone hole, the anchor begins to rotate or reorient, and while the main body of the insertion tool remains parallel to the bone hole, the insertion end of the insertion tool bends. Eventually the anchor is fully disposed in the bone hole, thereby allowing the insertion end of the insertion tool to return to its initially straight configuration and deploy the suture anchor. Once the suture anchor is secured in its final position, the insertion tool is disengaged from the suture anchor and removed. Col. 11, lines 10-42.

Accordingly, further because neither Pedlick nor Bartlett, either alone or in combination, teaches or even suggests a suture anchor that is configured to toggle and anchor inside a bone cavity based on tension being applied to a suture in the suture channel, the Examiner's proposed combination does not render independent claims 1, 15, and 19 obvious.

c. There Is No Suggestion or Motivation to Combine Bartlett with Pedlick

While the combination of Pedlick and Bartlett fails to teach or even suggest multiple recitations of independent claims 1, 15, and 19, the Examiner's rejection fails further because there is no rational underpinning for making the combination proposed by the Examiner.

In accordance with the procedures outlined by the Manual of Patent Examining Procedure (MPEP) in light of *KSR International Co. v. Teleflex Inc.*, there must be one or more clearly articulated reasons as to why the claimed invention would have been obvious in order to support any rejection under 35 U.S.C. §103.

> The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. __, __, 82 USPQ2d 1385, 1396 (2007) notes that the analysis supporting a rejection under 35 U.S.C. 103 ***should be made explicit.*** The Federal Circuit has stated that "rejections on obviousness cannot be sustained with mere conclusory statements; instead, there ***must be some articulated reasoning with some rational underpinning*** to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). See also *KSR*, 550 U.S. at __, 82 USPQ2d at 1396 (quoting Federal Circuit statement with approval.)

MPEP § 2142; *emphasis added.* Moreover, the Examiner must guard against impermissible hindsight that results from the knowledge of the invention of the present application and the Examiner may not "use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious." *In re Kotzab*, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) (citation omitted).

Neither Pedlick nor Bartlett provides any suggestion or motivation for the Examiner's proposed combination of substituting the suture opening or channel 5 of the Pedlick anchor with the suture accessory bore 36 of the Bartlett anchor such that the bore is offset from the center of

the anchor in a direction opposite the direction of the flared portion. The Examiner asserts that a person of ordinary skill in the art would have been motivated to make such a substitution both for the purpose of toggling the anchor and preventing a detrimental effect on the strength of the suture anchor. Paragraph 12, page 6, lines 1-7 of the Office Action. As discussed in section VII(B)(2)(b) above, neither Pedlick nor Bartlett teach a laterally offset suture channel or bore "for the purpose of toggling the anchor." The suture opening or channel 5 of the Pedlick anchor is not laterally offset at all, and, presumably, the anchor is sufficiently strong for its intended purpose.

Likewise, Bartlett also does not teach a laterally offset suture channel or bore "for the purpose of toggling the anchor," as its anchor, like Pedlick's anchor, is toggled by the insertion tool. According to Bartlett, "[t]he location of accessory bore 36 is selected to have the smallest effect on the strength of the suture anchor because of the deficit of suture anchor material." Col. 8, lines 53-56. This makes sense in the context of Bartlett, as can be seen in FIGS. 3 and 4, which are reproduced below, because Bartlett provides a through-bore (34) at an angle through the anchor body for mating with the insertion tool – the placement of the suture bore (36) would need to be driven by concerns about integrity.

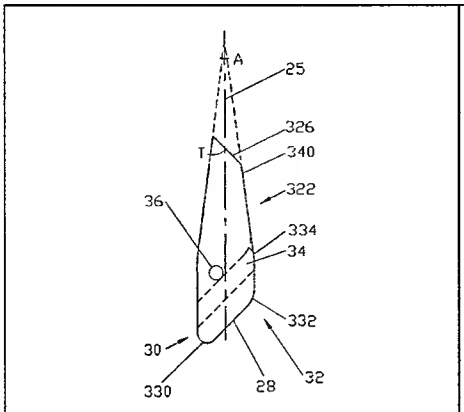


FIG. 3

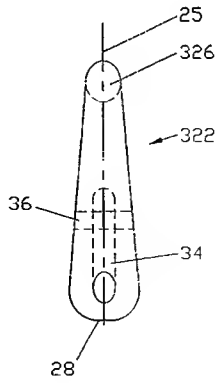


FIG. 4

In sharp contrast to the situation in Bartlett, Pedlick does not weaken its anchor body by providing a through-bore for attachment to an insertion tool. As a result, Pedlick places its suture holding bore right on the longitudinal axis of the suture body (that is, the portion of the

anchor that is not the "flared portion"), as this would be where the most material is. Accordingly, "the strength of the suture anchor" is not a rational basis for moving Pedlick's suture bore laterally from the longitudinal axis as this would only make Pedlick's suture body weaker. Still further, if one were motivated to move Pedlick's suture bore off-axis for reasons of strength of the suture anchor, a person of ordinary skill would be motivated to move it ***toward*** the flare as there is more material there rather than in the ***opposite*** direction as is expressly recited in the claim.

In summary, the Examiner posits two reasons for modifying Pedlick. One reason is "the strength of the suture anchor." This reason is at best not rational, and would actually motivate a person of ordinary skill to do the opposite of what is recited in the claim. The second reason for moving the suture bore off-axis, so that the suture can toggle the anchor, can be found only in Applicants' specification and nowhere else in the art. This is the very definition of hindsight reasoning using Applicants' invention as a template to pick and choose features from the art. *KSR* prohibits this. Accordingly, there is no motivation to make the proposed modification.

d. The Claimed Suture Anchor and System for Anchoring Tissue to a Bone Is Not Obvious in View of Secondary Considerations

The fact that the proposed combination is not obvious is further supported by secondary considerations such as the previously unachieved advantages that result from the claimed invention and the commercial success that has resulted from the same.

The Examiner asserts that no advantage is achieved or problem solved by forming a suture channel in the elongate body of an anchor having a centerline that is laterally offset with respect to the longitudinal axis of symmetry of the body in a direction opposite to the direction of the flared portion of the anchor. Paragraph 13, page 6, lines 8-14 of the Office Action. This assertion, however, completely ignores the Lizardi Declaration in which one of the inventors, Jose E. Lizardi, explains the advantages that were achieved and the problems that were solved as a result of the present invention.

Prior to the present invention, the use of suture anchors in small bones were limited primarily to suture anchors that used screws, threads, and barbs to attach tissue to bone. Paragraph 7, page 3, lines 5-6 of the Lizardi Declaration While toggling anchors were known at the time of the invention, they were used in larger bones, such as bones of the shoulder disclosed for procedures described in Pedlick. *Id.* at page 4, lines 1-7 of the Lizardi Declaration. A goal the inventors sought to achieve, and which was successfully achieved as a result of the present invention, was to develop a smaller toggling anchor that could bring the advantages in ease of use and grip in bone of toggling anchors to procedures in smaller bones that lacked the space for such toggling anchors in the past. By using the claimed configuration, an advantage was achieved because the anchor could be toggled simply by putting tension on the suture thread – using the anchor inserter to toggle the anchor was not required (and indeed, there would not be room for it) – and having the anchor toggle in a predetermined direction and way by placing the suture channel in its recited transverse and offset configuration. A further advantage was achieved because the toggling could be directed, therefore allowing a surgeon to plan for the directed toggling and choosing an orientation of the bone hole in which there was sufficient room for the anchor to toggle, even within small bone spaces. *See id.* at paragraphs 4, 6, and 7. As a result of the present invention, no longer were screws, threads, and barbs needed to attach tissue to bone in procedures for small bones, but rather, togging anchors could now be used. Thus, despite the Examiner's assertions, the present invention both provides an advantage over anchors that were previously used in procedures for small bones,[1] and solves a problem of not being able to use toggling anchors in small bones.

The fact that the present invention both provides advantages over the prior art and solves problems that existed in the field is further supported by the commercial success experienced by suture anchors that are still sold using the claimed configuration. The commercial success of a claimed invention is a secondary consideration that, when presented, is evaluated in determining whether the claimed invention was obvious. *See* MPEP § 716. Commercial success is an

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[1] Although the Examiner asserts that the Pedlick and Bartlett anchors are configured for use in small bones, the references and the Declaration make clear that they are not configured for such use, and thus, they would not perform equally well as the Examiner argues.

indicator that an invention may not be obvious provided that there is a nexus between the claimed invention and the commercial success. MPEP § 716.03.

Following the present invention, in 2003 the assignee of the present application released two products based upon the claimed design, the MiniLok and MicroFix suture anchors. Paragraph 8, page 4, lines 9-11 of the Lizardi Declaration. The marketing and sales for the suture anchors were performed in the normal course of business, and the suture anchors have sold well since that time and are still offered for sale today, in particular for uses with surgeries involving the attachment of tissue to bones in the hand and face (i.e., small bones). *Id.* at lines 11-14 and 17-18. "Doctors and others purchasing the suture anchors prefer the toggling suture anchors for such use as opposed to the thread or screw suture anchors because the toggling causes less damage to the bone and causes a more secure and exact fit between the tissue and the bone the tissue is being attached to." *Id.* at lines 14-17. "The commercial success of the suture anchors continue even today as the advantages provided by the first toggling suture anchors for use in small areas such as bones in the hand and face are still realized and appreciated as an industry standard." *Id.* at lines 18-21.

Accordingly, further evidence of nonobviousness is provided by achieved advantages, problems solved, and commercial success that resulted from the claimed configuration of a suture anchor.

Thus, in light of the fact that the Examiner's proposed combination does not lead to the claimed invention, that there is no suggestion or motivation to make the Examiner's proposed combination, and that the secondary considerations further support the fact that the claimed invention is not obvious, claims 1, 15, and 19, as well as claims 2-5, 8-14, and 16-18 which depend therefrom, distinguish over the combination of Pedlick and Bartlett and represent allowable subject matter.

3. Pedlick in View of Bartlett Further Fails to Render Obvious Dependent Claims 2, 3, 17, and 18

Claims 2, 3, 17, and 18 are patentable at least because they depend from allowable base claims 1 and 15, however, they are further patentable because the limitations of each of claims 2,

3, 17, and 18 are not taught or suggested by either Pedlick or Bartlett, either alone or in combination.

a. Pedlick in View of Bartlett Fails to Teach or Even Suggest a Suture Anchor in which the Elongate Body Is in the Range of about 2 to about 6 mm

Dependent claim 2 is further patentable over Pedlick in view of Bartlett because neither reference teaches or even suggests a suture anchor in which a length of the elongate body of the anchor is in the range of about 2 to about 6 mm. The Examiner argues that Pedlick discloses a suture anchor that has a 3 mm diameter and a suture anchor that has an overall size that is smaller than conventional bone anchors. Paragraph 14, page 6, lines 15-17 of the Office Action. The Examiner, relying on *In re Aller*, also argues that determining the optimum or workable range of a claim where the general conditions of a claim are disclosed involves only routine skill in the art. *Id.* at page 6, line 17 to page 7, line 1. Relying on extrinsic evidence, the Examiner asserts that U.S. Patent No. 6,280,474 to Cassidy ("Cassidy") discloses a bone anchor that can be used to attach small bone to small bone or soft tissue to bone in which a length is between 3 mm and 30 mm. *Id.* at page 7, lines 1-5.

While Pedlick does disclose a suture anchor having a ***diameter*** of 3 mm, the section that the Examiner argues includes a disclosure that the suture anchor has an overall size that is smaller than conventional bone anchors, i.e., col. 9, lines 20-25, states nothing of the sort. In fact, as discussed at length throughout this brief, the present invention is particularly advantageous because it recites a toggling suture anchor that can be used in small bones, unlike the cited prior art references which toggle in larger bones. Further, while the ***diameter*** of the suture anchor 1 in Pedlick, which is defined by a length of the abutment end 2, may be 3 mm, the length of the elongate body, which is defined by a full length of the body, is larger. *See* col. 9, lines 23-26. In particular, Pedlick discloses that the hole in which the suture anchor 1 is disposed has a diameter of 5 mm, and as illustrated in FIGS. 9 and 10, which are reproduced below, the length of the body is approximately greater than the diameter of the bone hole because the ends of the anchor 1 extend outside of the hole and into the softer cancellous layer surrounding the

hole. *Id.* Thus, Pedlick fails to teach or even suggest a suture anchor having an elongate body with a length in the range of about 2 to about 6 mm.

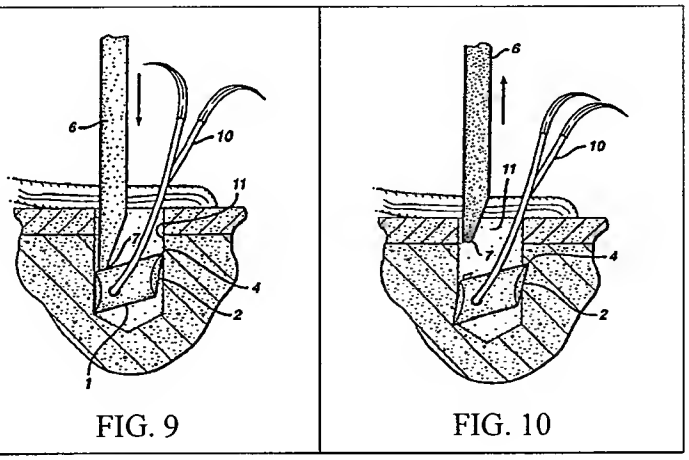


FIG. 9 FIG. 10

Bartlett fails to remedy the deficiencies of Pedlick. Bartlett teaches that the length of suture anchors 20, 22, 322, and 722 is preferably approximately 1.156 cm and the length of suture anchor 522 is preferably approximately 1.118 cm. Col. 5, lines 31-34. Both of these lengths are significantly larger than the recited range of about 2 to about 6 mm.

Still further, the reliance by the Examiner on *In re Aller* is inapt. As § 2144.05(II)(B) of the MPEP notes:

> A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977).*

The Examiner provides no indication that the length of the elongate body is a result-effective variable. Neither Pedlick nor Bartlett recognizes or suggests that a length of the elongate body of the anchor is a result-effective variable. The Examiner asserts that Cassidy discloses a bone anchor that can be used to attach small bone to small bone or soft tissue to bone in which a length is between 3 mm and 30 mm, but Cassidy too fails to recognize this parameter as a result-effective variable. Without a determination that a parameter is a result-effective variable, an

optimum or workable range ***cannot*** be determined through routine experimentation, and thus a rejection on these grounds cannot be sustained.

The Examiner's reliance on Cassidy is also improper because a person of ordinary skill in the art would not rely on the teachings of Cassidy, which are directed to a device that swells in order to implant in bone, to modify the teachings of anchors that toggle, like the anchors of Pedlick and Bartlett. Cassidy teaches an implant made of a dehydrated, resorbable, swellable preformed body that, after insertion, anchors in hard tissue when the implant rehydrates and swells. Col. 8, lines 16-24. Regardless of the dimensions taught by Cassidy, the teachings are inapplicable to a toggling suture anchor. There is no plausible way to rely on the teachings of a swelling implant as described in Cassidy to arrive at a toggling suture anchor that has a length of an elongate body that is in the range of about 2 to about 6 mm. Any teachings from Cassidy cannot be combined with the teachings of either Pedlick or Bartlett to arrive at the claimed dimensions.

Accordingly, dependent claim 2 is further patentable over any combination of Pedlick, Bartlett, and Cassidy because none of the possible combinations teach or even suggest a suture anchor configured to toggle in which a length of the elongate body of the anchor is in the range of about 2 to about 6 mm.

b. Pedlick in View of Bartlett Fails to Teach or Even Suggest a System for Anchoring Tissue to Bone that Includes a Suture Anchor in which the Elongate Body of the Suture Anchor Is in the Range of about 2 to about 6 mm

Similarly, dependent claim 17 is further patentable over Pedlick in view of Bartlett because neither reference teaches or even suggests a system for anchoring tissue to bone that includes a suture anchor in which a length of the elongate body of the anchor is in the range of about 2 to about 6 mm. The Examiner also suggests that Cassidy discloses the claimed length range. As discussed above with respect to claim 2, none of Pedlick, Bartlett, and Cassidy, either alone or in combination, teach or even suggest a suture anchor in which a length of the elongate body of the anchor is in the range of about 2 to about 6 mm. Further, the determination of the

optimum or workable range of the claimed length does not involve only routine skill in the art because such determination is not made based on a result-effective variable. Accordingly, dependent claim 17 is further patentable over any combination of Pedlick, Bartlett, and Cassidy.

c. Pedlick in View of Bartlett Fails to Teach or Even Suggest a Suture Anchor in which a Width of the Second Trailing End Is about 1 mm to about 3 mm at Its Widest Portion

Dependent claim 3 is further patentable over Pedlick in view of Bartlett because neither reference teaches or even suggests a suture anchor in which a width of the second trailing end of the anchor is about 1 mm to about 3 mm at its widest portion. The Examiner argues that Pedlick discloses a suture anchor that has a 3 mm diameter and a suture anchor that has an overall size that is smaller than conventional bone anchors. Paragraph 14, page 6, lines 15-17 of the Office Action. The Examiner, relying on *In re Aller*, also argues that determining the optimum or workable range of a claim where the general conditions of a claim are disclosed involves only routine skill in the art. *Id.* at page 6, line 17 to page 7, line 1. Relying on extrinsic evidence, the Examiner asserts that Cassidy discloses a bone anchor that can be used to attach small bone to small bone or soft tissue to bone in which a width is between 1 mm and 6 mm. *Id.* at page 7, lines 1-5.

As explained above in section VII(B)(3)(a), the section of Pedlick that the Examiner argues includes a disclosure that the suture anchor has an overall size that is smaller than conventional bone anchors, i.e., col. 9, lines 20-25, does not include such a statement or implication. While a suture anchor that has an overall size that is smaller than conventional toggling bone anchors is a distinct feature of the present invention, Pedlick does not provide any such teachings. Pedlick does disclose a suture anchor having a diameter of 3 mm, but this is considerably larger than the recited range of widths of the trailing edge – 1 mm to about 3 mm at its widest portion. *See* col. 9, lines 23-26 of Pedlick.

Bartlett fails to remedy the deficiencies of Pedlick. Bartlett teaches that the thickest diameter of the suture anchors 20, 22, 322, and 722 is preferably approximately 0.297 cm and the diameter of the cylindrical portion of suture anchor 522 is preferably approximately 0.287 cm.

Col. 5, lines 35-38. Both of these diameters are significantly larger than the recited range of about 1 mm to about 3 mm at its widest portion.

Further, similar to determining the length of the elongate body of the anchor, determining the optimum or workable range of the claimed width also does not involve only routine skill in the art because such determination is not a result-effective variable. The Examiner provides no indication that the width of the second trailing end is a result-effective variable. Neither Pedlick nor Bartlett recognizes or suggests that a width of the second trailing end is a result-effective variable. The Examiner asserts that Cassidy discloses a bone anchor that can be used to attach small bone to small bone or soft tissue to bone in which a width is 1 mm to about 6 mm, but Cassidy too fails to recognize this parameter as a result-effective variable. Without a determination that a parameter is a result-effective variable, an optimum or workable range cannot be determined through routine experimentation, and thus a rejection on these grounds cannot be sustained.

The Examiner's reliance on Cassidy with respect to the claimed width is also improper because a person of ordinary skill would not rely on the teachings of the swellable implant of Cassidy to modify the teachings of anchors that toggle, like the anchors of Pedlick and Bartlett. Regardless of the dimensions taught by Cassidy, the teachings are inapplicable to a toggling suture anchor. There is no plausible way to rely on the teachings of a swelling implant as described in Cassidy to arrive at a toggling suture anchor that has a width of the second trailing end that is about 1 mm to about 3 mm at its widest portion. Any teachings from Cassidy cannot be combined with the teachings of either Pedlick or Bartlett to arrive at the claimed dimensions.

Accordingly, dependent claim 3 is further patentable over any combination of Pedlick, Bartlett, and Cassidy because none of the possible combinations teach or even suggest a suture anchor configured to toggle in which a width of the second trailing end of the anchor is about 1 mm to about 3 mm at its widest portion.

d. Pedlick in View of Bartlett Fails to Teach or Even Suggest a System for Anchoring Tissue to Bone that Includes a Suture Anchor in which a Width of the Second Trailing End of the Suture Anchor Is about 1 mm to about 3 mm at Its Widest Portion

Similarly, dependent claim 18 is further patentable over Pedlick in view of Bartlett because neither reference teaches or even suggests a system for anchoring tissue to bone that includes a suture anchor in which a width of the second trailing end of the anchor is about 1 mm to about 3 mm at its widest portion. The Examiner also suggests that Cassidy discloses the claimed width range. As discussed above with respect to claim 3, none of Pedlick, Bartlett, and Cassidy, either alone or in combination, teach or even suggest a suture anchor in which a width of the second trailing end of the anchor is about 1 mm to about 3 mm at its widest portion. Further, the determination of the optimum or workable range of the claimed width does not involve only routine skill in the art because such determination is not made based on a result-effective variable. Accordingly, dependent claim 18 is further patentable over any combination of Pedlick, Bartlett, and Cassidy.

C. Claims 2, 3, 14, 17, and 18 Are Not Obvious Over Haut

The Examiner also rejects claims 2, 3, 14, 17, and 18 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 7,320,701 to Haut et al. ("Haut"). As established in the response to Office Action dated September 2, 2009, in view of a concurrently filed Declaration of Shelby L. Cook, Jose E. Lizardi, Karl S. Reese, and Thomas A. Shepard Pursuant to 37 C.F.R. § 1.131 that is attached hereto as Exhibit B ("the Inventors' Declaration"), and as agreed upon by the Examiner in the most recent Office Action, the subject matter as claimed in the present invention was invented and reduced to practice prior to June 2, 2003, which is the effective date of Haut. Paragraph 3, lines 5-8 of the Office Action. Thus, Haut is not proper prior art as applied to the present invention.

Despite agreeing with Applicants, the Examiner rejects claims 2, 3, 14, 17, and 18 in view of Haut. Applicants assume this means that the Examiner does not believe the recitations of claims 2, 3, 14, 17, and 18 are taught in Exhibit A of the Inventors' Declaration.

Claims 2, 3, 14, 17, and 18 are patentable at least because they depend from allowable base claims 1 and 15. Claims 2, 3, 17, and 18 are further patentable because Haut is not proper prior art with respect to the limitations recited therein.

Each of claims 2, 3, 17, and 18 are directed to specific dimensions of the recited suture anchor. Claims 2 and 17 recite a length of the elongate body of the anchor that is in the range of about 2 to about 6 mm, and claims 3 and 18 recite a width of the second trailing end of the anchor that is about 1 mm to about 3 mm at its widest portion. Exhibit A of the Inventors' Declaration illustrates one anchor in which a length of the elongate body is about 0.105 inches, which is the equivalent of about 2.667 mm, and a width of the second trailing end of the anchor that is about 0.064 inches, which is the equivalent of about 1.6256 mm. Page 1 of Exhibit A of the Inventors' Declaration. A second anchor illustrated in Exhibit A of the Inventors' Declaration discloses a length of the elongate body that is about 0.200 inches, which is the equivalent of about 5.08 mm, and a width of the second trailing end of the anchor that is about 0.091 inches, which is the equivalent of about 2.3114 mm. Page 2 of Exhibit A of the Inventors' Declaration. Thus, the Inventors' Declaration clearly establishes that the dimensions recited in claims 2, 3, 17, and 18 were considered, invented, and reduced to practice prior to June 2, 2003, which is the effective date of Haut. Haut is not proper prior art with respect to any of claims 2, 3, 17, and 18 to the extent they could be written in independent form.

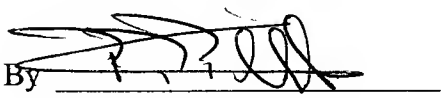
Accordingly, each of dependent claims 2, 3, 17, and 18 are further patentable over Haut because Haut is not proper prior art.

VIII. CONCLUSION

For the reasons noted above, Appellant submits that the pending claims define patentable subject matter. Accordingly, Appellant requests that the Examiner's rejection of these claims be reversed and that the pending application be passed to issue.

Dated: February 26, 2010

Respectfully submitted,



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IX. APPENDIX A: LISTING OF CLAIMS ON APPEAL

1. (Previously Presented) A suture anchor for anchoring tissue to a bone, comprising:

an elongate body defined by a longitudinal axis of symmetry, a first, leading end and a second, trailing end, the elongate body comprising two opposed surfaces between the first and second ends, and a plurality of sidewalls extending between the two opposed surfaces;

a flared portion formed on the second end and extending from one of the sidewalls, the flared portion being adapted to engage and anchor into bone tissue; and

a suture channel formed in the elongate body for passage of a suture strand therethrough, the suture channel extending between the two opposed surfaces, being oriented substantially transverse at right angles to the longitudinal axis of symmetry of the body, and having a centerline that is laterally offset with respect to the longitudinal axis of symmetry of the body in a direction opposite to the direction of the flared portion;

wherein the suture anchor is configured to toggle and anchor inside a bone cavity based on tension being applied to a suture in the suture channel.

2. (Previously Presented) The anchor of claim 1, wherein a length of the elongate body is in the range of about 2 to about 6 mm.

3. (Previously Presented) The anchor of claim 1, wherein a width of the second trailing end is about 1 mm to about 3 mm at its widest portion.

4. (Original) The anchor of claim 1, wherein the first, leading end is tapered.

5. (Original) The anchor of claim 4, wherein the first, leading end extends into a blunt tip having a continuous surface.

6. (Canceled).

7. (Canceled).

8. (Previously Presented) The anchor of claim 1, wherein the suture channel has a chamfered rim.

9. (Previously Presented) The anchor of claim 1, wherein the suture channel has a smooth rim.

10. (Original) The anchor of claim 1, wherein the flared portion has a shape effective to penetrate into bone.

11. (Original) The anchor of claim 10, wherein the flared portion includes a sharp edge.

12. (Original) The anchor of claim 10, wherein the flared portion includes a flat, bone-contacting face with a knife edge.

13. (Original) The anchor of claim 1, further including an insertion tool engaging bore extending into the elongate body from the second trailing end thereof.

14. (Original) The anchor of claim 1, wherein the elongate body is formed with a blue dye for visualization.

15. (Previously Presented) A system for anchoring tissue to a bone, comprising:

a bioabsorbable suture anchor having:

an elongate body defined by a longitudinal axis of symmetry, a first leading end and a second, trailing end, the elongate body comprising two opposed surfaces between the first and second ends, and a plurality of sidewalls extending between the two opposed surfaces;

a bore extending into the elongate body from the second trailing end thereof;

a flared portion formed on the second end and extending from one of the sidewalls, the flared portion being adapted to engage and anchor into bone tissue, wherein the

suture anchor is configured to toggle and anchor inside a bone cavity based on tension being applied to a suture in the suture channel; and

a suture channel formed in the elongate body for passage of a suture strand therethrough, the suture channel extending between the two opposed surfaces, being oriented substantially transverse at right angles to the longitudinal axis of symmetry of the body, and having a centerline that is laterally offset with respect to the longitudinal axis of symmetry of the body in a direction opposite to the direction of the flared portion;

a length of suture thread attached to the suture anchor; and

a suture anchor insertion tool, the tool having an elongate member with a proximal, handle end and a distal, attachment end.

16. (Original) The system of claim 15, wherein the proximal, attachment end of the suture anchor insertion tool includes an insertion tip configured to provide an interference fit with the bore of the suture anchor.

17. (Previously Presented) The system of claim 15, wherein a length of the elongate body is in the range of about 2 to about 6 mm.

18. (Previously Presented) The system of claim 15, wherein a width of the second trailing end is about 1 mm to about 3 mm at its widest portion.

19. (Previously Presented) A method of attaching tissue to a bone in a patient's body, comprising the steps of:

providing a system for anchoring tissue to bone, the system including a bioabsorbable suture anchor having an elongate body defined by a longitudinal axis of symmetry, a first leading end and a second, trailing end, the elongate body comprising two opposed surfaces between the first and second ends, and a plurality of sidewalls extending between the two opposed surfaces, a flared portion formed on the second end and extending from one of the sidewalls, the flared portion being adapted to engage and anchor into bone tissue, wherein the suture anchor is configured to toggle and anchor inside a bone cavity, and a suture

channel formed in the elongate body for passage of a suture strand therethrough, the suture channel extending between the two opposed surfaces, being oriented substantially transverse at right angles to the longitudinal axis of symmetry of the body, and having a centerline that is laterally offset with respect to the longitudinal axis of symmetry of the body in a direction opposite to the direction of the flared portion, the system further including a length of suture thread attached to the suture anchor;

forming a bone cavity in the bone where the tissue is to be anchored;

securing the suture strand to a portion of tissue to be attached to the bone;

inserting the suture anchor at least partially within the bone cavity; and

toggling the suture anchor by pulling on the attached suture strand such that the flared portion of the anchor penetrates into an inner surface of the bone cavity.

20-25. (Canceled).

X. APPENDIX B: LISTING OF EVIDENCE

EXHIBIT A – Declaration of Jose E. Lizardi Pursuant to Rule 132

- Entered by Applicants in Response dated January 22, 2008.
- All references cited in the Declaration can be found in the application file and cited in an Information Disclosure Statement concurrently filed with the Declaration.

EXHIBIT B – Declaration of Shelby L. Cook, Jose E. Lizardi, Karl S. Reese, and Thomas A. Shepard Pursuant to 37 C.F.R. § 1.131

- Entered by Applicants in Response dated September 2, 2009.
- Includes its own Exhibit A, which is two pages of drawings of the claimed invention (dates redacted) that were prepared before June 2, 2003, i.e., the § 102(e) date of U.S. Patent No. 7,320,701 to Haut et al.

XI. APPENDIX C: LISTING OF RELATED PROCEEDINGS

None.

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